

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: REIMANN=1

In re Application of:

REIMANN et al.

Appln. No.: 09/241,595

Appln. No.: 09/241,595

Filed: February 2, 1999

For: DELIVERY OF IMMUNOGENIC

MOLECULES VIA HBsAg
PARTICLES

ACCOMPANDA

Confirmation No.: 8928

Reimann No.: 1632

Reiman

# INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents U.S. Patent and Trademark Office 2011 South Clark Place Customer Window, Mail Stop DD Crystal Plaza Two, Lobby, Room 1B03 Arlington, Virginia 22202

#### Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

#### (Check one of the boxes A-D)

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[ ] B. before the mailing date of a first Office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.

[X] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

(Check one of the boxes "i" and "ii" below:)

- [] i. Counsel certifies that, upon information and belief, each item of information listed herein was either
  - [] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
  - [] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

### (use one and delete other of following)

[] ii. A check (check no. \_\_\_\_\_) for the fee set forth in §1.17(p), presently believed to be \$180, is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

· In re Appln. No.

[X] ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

[ ] D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant(s) state as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein was either

(Check one of the boxes "a" and "b" below)

- [ ] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- [ ] (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

(use one and delete other of following and this note) A check (check no. \_\_\_\_) for/ Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(i), presently believed to be \$180 is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

[X] 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., Form PTO/SB/08A) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate)

- [] A. Document(s) \_\_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_\_, and, in accordance with §1.98(c), only a copy of each of the latter documents is enclosed.
- [ ] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications) Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 (or PTO/SB/08A) from the files of the prior application(s) or a fresh PTO-1449 (or PTO/SB/08A) listing these documents, and request that they be considered and made of record in accordance with \$1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

[] C. Document(s) \_\_\_\_\_\_\_ is (are) U.S. patent(s) and/or published application(s). As this is a U.S. application filed after June 30, 2003, or an entry into national stage under 35 USC §371 after June 30, 2003, the requirement to file copies of such U.S. patents or published applications has been waived. (Office of Patent Legal Administration - Pre O.G. Notice of July 11, 2003).

· In re Appln. No.

	3. Document(s) is (are) not in the
English states:	language. In accordance with §1.98(c), Applicant(s)
	[] An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
	[] A concise explanation of the relevance of document(s) is found in the attached search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
	[] A concise explanation of the relevance of document(s) is set forth as follows:
	(insert concise explanation of relevance)
	[] A concise explanation of the relevance of document(s) can be found on page(s) of the specification.
	[ ] A concise explanation of document(s) can be found on the attached sheet.
[X]	4. No explanation of relevance is necessary for
locuments	s in the English language (see reply to Comments 67 and

- d language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- 5. Other information being provided for the examiner's consideration follows:

(insert other information)

In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56

· In re Appln. No. (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK

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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known				
Application Number	09/241,595			
Filing Date	February 2, 1999			
First Named Inventor	REIMANN et al.			
Group Art Unit	1632			
Examiner Name	Anne M. S. Wehbe			
Attorney Docket Number	REIMANN=1			

	U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	U.S. Paten Number	t Document Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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				FOREIG	N PATENT DOCUMENTS			
		Foreign Patent Number				Date of		
Examiner Initials*	Cite No. <sup>1</sup>	Office <sup>3</sup>	Number	Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Document	Publication of Cited Document MM-DD- YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>®</sup>
	AA	PCT	WO 98/52962		CAULFIELD	11-26-1998		
	AB	EP	0 326 109 A2		NEURATH	08-02-1989		

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	AC	QU et al., Humoral immune response enhanced by immunization with anti-HBs and HbsAg complex plus DNA vaccine, Chemical Abstracts, page 539
	AD	DAVIS et al., CpG DNA is a potent enhancer of specific immunity in mice immunized with recombinant Hepatitis B surface antigen, The Journal of Immunology, 160:870-876 (1998)
	AE	SCHIRMBECK et al., Nucleic acid vaccination primes hepatitis B virus surface antigen-specific cytotoxic T lymphocytes in nonresponder mice, <u>Journal of Virology</u> , 5929-5934 (1995)
	AF	SCHIRMBECK et al., Enhancing the immunogenicity of exogenous Hepatitis B surface antigen-based vaccines for MHC-O-restricted T cells, Biol. Chem., 380:285-291 (1999)
	AG	PUZO, The carbohydrate- and lipid- containing cell wall of mycobacteria, phenolic glycolipids: structure and immunological properties, Microbiology, 17:305-327
	АН	YAMAMOTO et al., Ability of oligonucleotides with certain palindromes to induce interferon production and augment natural killer cell activity is associated with their base length, Antisense Research and Development, 4:119-122 (1994)

Examiner Signature	Dat Cor	e nsidered		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

SEP 0 % 200:



Complete if Known Substitute for form 1449A/PTO 09/241,595 **Application Number INFORMATION DISCLOSURE** February 2, 1999 Filing Date STATEMENT BY APPLICANT **First Named Inventor** REIMANN et al. Group Art Unit 1632 (use as many sheets as necessary) Examiner Name Anne M. S. Wehbe Sheet of 2 Attorney Docket Number REIMANN=1

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	Al	FELGNER et al., Asymmetric incorporation of trisialoganglioside into dipalmitoylphosphatidylcholine vesicles, Biochemistry, 20:2168-2172 (1981)	
	AJ	WONG et al., Glycolipid transfer protein from bovine brain, <u>Biochemistry</u> , 23:6498-6505 (1984)	
	AK	WOOLDRIDGE et al., Immunostimulatory oligodeoxynucleotides containing CpG motifs enhance the efficacy of monoclonal antibody therapy of lymphoma, <u>Blood</u> , 89(8):2994-2998 (1997)	
	AL	NGUYEN et al., Contrasting effects of T cell growth factors on T cell responses to melanoma in vitro, Cancer Immunol. Immunother., 43:345-354 (1997)	
	AM	WEINER et al., Immunostimulatory oligodeoxynucleotides containing the CpG motif are effective as immune adjuvants in tumor antigen immunization, Proc. Natl. Acad. Sci. USA, 94:10833-10837 (1997)	
	AN	LOWRY et al., Protein measurement with the folin phenol reagent, Department of Pharmacology, 265-275 (1951)	
	AO	YAMAMOTO et al., Unique palindromic sequences in synthetic oligonucleotides are required to induce INF and augment INF-mediated natural killer activity, <u>The Journal of Immunology</u> , 148:4072-4076 (1992)	
	AP	GEISSLER et al., Enhancement of cellular and humoral immune responses to Hepatitis C virus core protein using DNA-based vaccines augmented with cytokine-expressing plasmids, The Journal of Immunology, 1231-1237 (1997)	
	AQ	YACHI et al., Distribution of liposomes containing mannobiose esters of fatty acid in rats, <u>J. Microencapsulation</u> , 12(4)377-388 (1995)	
	AR	PERIN et al., Evaluation of possible interference of anti-inflammatory drugs upon scintigraphic imaging with macrophage targeting 99mTc-J001X: effects of methylprednisolone, dexamethasone, indomethacin and methotrexate, Nucl. Med. Biol., 21(8)1093-1100 (1994)	
	AS	TALMON, Transmission electron microscopy of complex fluids: The state of the art, <u>Ber. Bunsenges. Phys. Chem.</u> , 100:364-372 (1996)	
	AT	DELPHEYROUX et al., A poliovirus neutralization epitope expressed on hybrid Hepatitis B surface antigen particles, Science, 233:472-475 (1986)	
277			
	7		

Date

Considered

IEUH CENTER 16JN/200

Examiner

Signature

<sup>\*</sup> EXAMPLER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.